

such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall (A) issue an order approving the application if the Secretary then finds that none of the grounds for denying approval specified in paragraph (3) applies, or (B) give the applicant notice of an opportunity for a hearing before the Secretary under paragraph (3) on the question whether such application is approvable. The procedure governing such a hearing shall be the procedure set forth in the last two sentences of subsection (c)(1).

“(3) If the Secretary, after due notice to the applicant in accordance with paragraph (2) and giving the applicant an opportunity for a hearing in accordance with such paragraph, finds, on the basis of information submitted to the Secretary as part of the application, on the basis of a preapproval inspection, or on the basis of any other information before the Secretary—

“(A) that the application is incomplete, false, or misleading in any particular;

“(B) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

“(C) that the facility manufactures animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture or labels animal feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are published pursuant to subsection (i), the Secretary shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (C) do not apply, the Secretary shall issue an order approving the application. An order under this subsection approving an application for a license to manufacture animal feeds bearing or containing new animal drugs shall permit a facility to manufacture only those animal feeds bearing or containing new animal drugs for which there are in effect regulations pursuant to subsection (i) relating to the use of such drugs in or on such animal feed.

“(4)(A) The Secretary shall, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feeds bearing or containing new animal drugs under this subsection if the Secretary finds—

“(i) that the application for such license contains any untrue statement of a material fact; or

“(ii) that the applicant has made changes that would cause the application to contain any untrue statements of material fact or that would affect the safety or effectiveness of the animal feeds manufactured at the facility unless the applicant has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application.

If the Secretary (or in the Secretary's absence the officer acting as the Secretary) finds that there is an imminent hazard to the health of humans or of the animals for which such animal feed is intended, the Secretary may suspend the license immediately, and give the applicant prompt notice of the action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence shall not be delegated.

“(B) The Secretary may also, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feed under this subsection if the Secretary finds—

“(i) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under paragraph (5)(A) of this subsection or section 504(a)(3)(A), or the applicant has refused to permit access to, or copying or verification of, such records as required by subparagraph (B) of such paragraph or section 504(a)(3)(B);

“(ii) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Secretary, specifying the matter complained of;

“(iii) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

“(iv) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the facility has manufactured, processed, packed, or held animal feed bearing or containing a new animal drug adulterated under section 501(a)(6) and the facility did not discontinue the manufacture, processing, packing, or holding of such animal feed within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

“(C) The Secretary may also revoke a license to manufacture animal feeds under this subsection if an applicant gives notice to the Secretary of intention to discontinue the manufacture of all animal feed covered under this subsection and waives an opportunity for a hearing on the matter.

“(D) Any order under this paragraph shall state the findings upon which it is based.

“(5) When a license to manufacture animal feeds bearing or containing new animal drugs has been issued—

“(A) the applicant shall establish and maintain such records, and make such reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approval application filed under subsection (b), as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether this is or may be ground for invoking subsection (e) or paragraph (4); and

“(B) every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

“(6) To the extent consistent with the public health, the Secretary may promulgate regulations for exempting from the operation of this subsection facilities that manufacture, process, pack, or hold animal feeds bearing or containing new animal drugs.”.

(c) TRANSITIONAL PROVISION.—A person engaged in the manufacture of animal feeds bearing or containing new animal drugs who

holds at least one approved medicated feed application for an animal feed bearing or containing new animal drugs, the manufacture of which was not otherwise exempt from the requirement for an approved medicated feed application on the date of the enactment of this Act, shall be deemed to hold a license for the manufacturing site identified in the approved medicated feed application. The revocation of license provisions of section 512(m)(4) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, shall apply to such licenses. Such license shall expire within 18 months from the date of enactment of this Act unless the person submits to the Secretary a completed license application for the manufacturing site accompanied by a copy of an approved medicated feed application for such site, which license application shall be deemed to be approved upon receipt by the Secretary.

## NOTICE OF HEARING

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Mr. LUGAR. Mr. President, I would like to announce that the Senate Committee on Agriculture, Nutrition, and Forestry will hold a full committee hearing on Wednesday, October 2, 1996, at 9 a.m. in SR-328A to discuss renewable fuels and the future security of U.S. energy supplies.

## AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON ARMED SERVICES

Mr. BROWN. Mr. President, I ask unanimous consent that the Committee on Armed Services be authorized to meet at 2 p.m. on Wednesday, September 25, 1996, in open session, to receive testimony on the impact of the Bosnian elections and the deployment of United States Military Forces to Bosnia and the Middle East.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON ARMED SERVICES

Mr. BROWN. Mr. President, I ask unanimous consent that the Committee on Armed Services be authorized to meet on Tuesday, September 24, 1996, at 3:30 p.m. in executive session, to consider certain pending military nominations.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

Mr. PRESSLER. Mr. President, I ask unanimous consent that the Committee on Commerce, Science, and Transportation be allowed to meet during the Tuesday, September 24, 1996 session of the Senate for the purpose of conducting a hearing on S. 1860, the Auto Choice Reform Act.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FOREIGN RELATIONS

Mr. BROWN. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Tuesday, September 24, 1996, at 10 a.m. to hold a hearing.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### COMMITTEE ON GOVERNMENTAL AFFAIRS

Mr. BROWN. Mr. President, I ask unanimous consent on behalf of the Governmental Affairs Committee to meet on Tuesday, September 24, at 10 a.m. for a hearing on the S. 1724, Freedom from Government Competition Act of 1996.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### COMMITTEE ON INDIAN AFFAIRS

Mr. BROWN. Mr. President, I ask unanimous consent that the Committee on Indian Affairs be authorized to meet during the session of the Senate on Tuesday, September 24, 1996, at 9:30 a.m. in room 106 of the Dirksen Senate Office Building to conduct a hearing on tribal sovereign immunity.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### SPECIAL COMMITTEE ON AGING

Mr. COHEN. Mr. President, I ask unanimous consent that the Special Committee on Aging be authorized to meet during the session of the Senate on Tuesday, September 24, at 9 a.m. to hold a hearing to discuss Social Security reform.

The PRESIDING OFFICER. Without objection, it is so ordered.

### NOTICE OF INTENTION TO SUSPEND THE STANDING RULES OF THE SENATE

Mr. LOTT. Mr. President, pursuant to rule 5, paragraph 1 of the Standing Rules of the Senate, I hereby give written notice to suspend rule 28 of the Standing Rules of the Senate, titles 3 and 6 of the Budget Act and all provisions of the budget resolutions for consideration of the conference report to accompany H.R. 3610, the DOD appropriations bill.

### ADDITIONAL STATEMENTS

#### UNITED STATES' RELATIONSHIP WITH NORTH KOREA

• Mr. SIMON. Mr. President, one of the Members of Congress who has contributed significantly more than most of us is Congressman TONY HALL.

His emphasis on helping people in need has sharpened the conscience of many policymakers, though it has not sharpened it enough.

He has provided leadership in areas that most Members of Congress ignore, such as Eritrea.

Recently he went to North Korea, and he testified before the Subcommittee on East Asian and Pacific Affairs of the Senate Foreign Relations Committee.

It is a remarkable insight into the leadership that is needed in regard to the tense situation in Korea.

Nowhere do we have as many troops facing each other as we do between North Korea and South Korea and that

problem is compounded by the fact that there is no communication between the two countries.

Mr. President, I ask that Congressman HALL's remarks be printed in the RECORD.

The remarks follow:

#### TESTIMONY OF U.S. REPRESENTATIVE TONY P. HALL

Good morning. I want to thank you for inviting me to testify today, Mr. Chairman, and to thank both you and Senator Robb for the focus you are bringing to the United States' relationship with North Korea.

I am convinced that our increasing contacts with North Korea can only benefit America's interests—and make the job of the 37,000 American troops stationed along the border with South Korea easier. And I am hopeful that our contacts also will help the people of North Korea who have suffered in their decades-long isolation, and are hurting badly today.

Our humanitarian work, our progress in dismantling North Korea's nuclear reactor and on missile technology controls, and the unprecedented joint investigation by U.S. and North Korean soldiers into the fate of missing servicemen—all of these mark a dramatic turn-around in a relationship that is in its fifth decade of military tension.

I believe our nation owes special thanks for these changes to former President Jimmy Carter, whose personal diplomacy laid the groundwork for peace two years ago. Senator Paul Simon, who with Senator Frank Murkowski travelled to North Korea at a crucial moment, and who has championed ideas that hold great promise for the future of both countries, also deserves recognition for his work. We ought to build on their success in seizing this historic opportunity.

#### NORTH KOREA'S FOOD SHORTAGE

The hunger and malnutrition that I saw in North Korea is different than famines I've seen in my visits to other countries. This is the only country I can remember where grown children are shorter than their parents. The starving is severe, especially when you compare North Koreans to their siblings and cousins in South Korea. And North Korea is the only place I've seen where parents and grandparents are giving their rations to their children in a desperate effort to protect them.

Today in North Korea, people are somehow surviving on rations of little more than 600 calories a day—just seven ounces of grain. That's not two bowls of rice, too much to die on, but not enough to live on and function. They are scrambling to supplement that starvation diet, but clearly having little success.

Nutritional standards say sedentary workers need about 2,000 calories a day to maintain their body weight—but people in North Korea cannot be sedentary. In two weeks, the harvest will be brought in with the aid of few animals and fewer machines. And if there is to be any hope for next year's harvest, the back-breaking work of rebuilding broken irrigation systems, roads, and other infrastructure must be completed.

Adults have lost an average of 30 pounds since January, according to Western aid workers I talked to there. According to our Ambassador to South Korea, James Laney, a North Korean soldier who defected to South Korea in mid-August weighed just 92 pounds. And there are many more measures of the extent of the suffering in North Korea in both the intelligence and in the unclassified reports of U.N. agencies, the International Red Cross, and charities that have visited North Korea.

For me, two things stand out in all of these measurements:

First, the bodies of most of the North Koreans that I saw are exhausted. Simply surviving this winter will be a tremendous physical challenge that many of them will not be able to meet.

Second, North Korea's land appears equally worn out. Food grows on any patch of land available—atop the rice paddy walls, along the shoulders of roads, in rivers' floodplains, on the slopes of steep hills. Land is not permitted to lie fallow, there is no investment in fertilizer and pesticides, deforestation leads to soil erosion that ruins once-productive land—and sorry yields are the result of it all.

North Korea's granaries were last full in 1992—but however self-inflicted the long-term problems may be, the country was overwhelmed by the worst natural disaster in its history last year. And this year, another severe flood struck the breadbasket provinces that produce 60 percent of North Korea's grain.

#### WHAT IS MISSING

What struck me most was not what I saw—but what was missing. There is an eerie silence in the capital, and in the villages that we visited in more than 20 hours on the road. You don't hear roosters crowing, and the air seems empty of birds—even of gulls in the seaside city of Haeju. You don't see cats, or rats, or cows or goats—or much sign of other animal life. Occasionally, in people's homes I saw dogs, but not a single puppy. According to some aid workers, the sight of a pregnant woman is increasingly rare, and a new maternity hospital never has more than 25 of its 250 beds filled. Certainly we saw no fat people—or anybody that bore much resemblance to their healthier siblings and cousins in South Korea.

Soldiers—and we saw a lot of individual soldiers throughout the capital and countryside—have the same hollow-cheeked look as civilians, and their uniforms hang very loosely on them. That may be the best evidence that most of North Korea's military isn't getting much more to eat than the rest of the people.

All of this added up to a nagging sense that we simply cannot know what is happening in North Korea. Aid workers speak in hushed tones when talk turns to what is happening in the mountains that make up 80 percent of North Korea. They can barely help the 1.5 million children and flood victims covered by the U.N.'s appeal for humanitarian aid; the remaining 20 million people are on their own.

Two American demographers, Nicholas Eberstadt of the American Enterprise Institute and Judith Banister, of the U.S. Census Bureau, have done statistical analysis of North Korea's population—and with your permission, Mr. Chairman, I would like to submit a letter for the record that Mr. Eberstadt is preparing. The gist of their finding is that half a million people are "missing." That is either (1) a statistical blip; or (2) a sign of severe changes in the birth and death rates. We cannot know which is true, but I believe the possibility of something that would affect 500,000 people deserves our concern.

#### NORTH KOREA'S OWN EFFORTS

I also want to comment briefly on the efforts that North Korea is making to ease suffering in its country. Its rations system now feeds the majority of the population, and by all accounts, it is meticulously fair. Ration cards measure out to three decimal points. A U.N. report issued Sept. 9 notes that sometimes there is not enough food to distribute the second of two monthly rations, but people do seem to share equally in the food available.

The system also appears to be exceptionally efficient. The first U.S. flag ship to visit